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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,776	11/27/2000	Joong Yeong Jeon	9250-2	4908

7590

07/29/2003

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/29/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/722,776

Applicant(s)

Jeon et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, and 6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicants amendment and response filed April 28, 2003 and May 13, 2003, respectively, have been received and entered. Claims 2, 4, 5, 7, 8, and 9-12 have been canceled. Consequently, claims 1, 3 and 6 are pending in the instant application.

Claim Rejections - 35 USC § 101

1. The rejection of claims 1-6 and 9-12 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1 and 6 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. This is a written description rejection.

It is noted that this rejection is withdrawn against claim 3 in view that claim 3 recites both activity (endonuclease) as well as physiochemical properties of 72.4 kd, Mg^{2+} dependent, and optimal pH of about 6.5-7.5.

This rejection is maintained as applied to claims 1 and 6. The claims have been amended to recite that the endonuclease (1) is isolatable from IM9 or phorbol ester-stimulated U937 cells

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and (2) has the indicated physical properties. While the indicated physical properties are sufficient to allow those of skill in the art to reasonably convey that Applicants had possession of the claimed invention, this does not allow those of skill in the art to recognize the genus solely from the starting material of IM9 or phorbol ester-stimulated U937 cells. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. This is analogous to Applicants claims, a claim to an endonuclease of undefined structure with a roadmap of where the protein can be isolated from. This simply does not meet the written description requirements. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted, given that the claims do not recite any structural limitations. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, Applicant's single enzyme, alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

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Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record in the Office Action mailed January 24, 2003, as well as the reasons cited above, this rejection is maintained.

3. The rejection of claims 3, 5, 9, and 11 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "approximately." is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1, 3 and 6 under 35 U.S.C. 102(b) as being anticipated by Kwon *et al* is maintained.

Applicants are asserting that the specification has been amended to indicate that the application is a continuation of PCT/KR98/00136, having an international filing date of May 30, 1998, and as such Kwon is not available as a prior art reference.

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Applicants arguments have been fully considered but are not found to be fully persuasive.

First, it is noted that Applicants Declaration recites a claim of priority under 35 USC 119 to a foreign application. However, while foreign priority may be afforded under 35 USC 119, a continuation of a PCT is not permitted under 35 USC 119. This continuation can only be made under 35 USC 120. Applicants Declaration does not recite any priority to any application under 35 USC 120. Accordingly, Applicants attempt to claim a continuation of PCT/KR98/00136 is simply not supported by Applicants Declaration. Consequently, the prior art document is an appropriate reference under the 35 USC 102 statute.

Claims 1, 3 and 6 are directed to a purified endonuclease which is secreted from a human B lymphoblastic IM9 cell line or a 12-tetradecanoylphorbol 13-acetate-treated U937 cell line and recognizes bacterial DNA as foreign agent and processes it to produce about 10bp single-stranded oligonucleotide including CpG motif which is involved in immune response.

Kwon *et al* (International Journal of Biochemistry and Cell Biology Vol. 30, February 1998, pp 217-223) disclose of a Mg^{2+} dependent endonuclease from IM9 cell lysates, with an optimum pH range of 6.5-7.5. (See abstract and page 220).

It is noted that Kwon *et al* do not characterize the endonuclease as one that recognized bacterial DNA as foreign and processes it to produce about 10 bp oligonucleotides including a CpG motif, however this is deemed to be an inherent property of the claimed endonuclease given that both the enzyme as claimed and disclosed by Kwon *et al* share:

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same activity (endonuclease)

Mg²⁺ dependent

obtained from same source (IM9) cell line

and same optimal pH range (6.5-7.5).

For reasons of record in Paper Number 14, as well as the reasons set forth above, this rejection is maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner

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can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

July 28, 2003